

SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION
CONTAINED IN THIS SUBMISSION

1. Passive Safety -

K 9628 SS

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- a. At all times the extent and duration of activity is determined by the therapist. (Appendix 1)
- b. The equipment provides an aid to the rehabilitation or training of the patient, but does not force the patient to undertake any activity. (Appendix 1)
- c. There is no energy exchange between exercise device and patient; (Appendix 1)
- d. The patient is not attached to the equipment in any way other than by the patients' grip. (Appendix 1)

2. Electrical Safety -

- a) Opto isolation of data outputs to 4Kv (Appendix 6)
- b) Isolation of low voltage DC power supply to 4Kv (Appendix 6)
- c) Primary insulation in addition to A and B (Appendix 5)

3. Effectiveness -

Penny and Giles Biometrics makes no claims for the effectiveness of this equipment, but wishes to direct the attention of the examiners to the reports included as the Verification and Validation section of this document.